Meeting of the
Pharmacy and Therapeutics Committee
April 20, 2009
Draft Minutes

Members Present:
Randy Axelrod, M.D., Chair
Mark Oley, R.Ph., Vice Chair
Roy Beveridge, M.D.
Gill Abernathy, M.S., R.Ph.
James Reinhard, M.D.
Rachel M. Selby-Penczak, M.D.
Renita Driver, Pharm.D.
Tim Jennings, Pharm.D.
Avtar Dhillon, M.D.

Absent:
Reuben Varghese, M.D.
Mariann Johnson, M.D.

DMAS Staff:
Patrick Finnerty, Agency Director
Cheryl Roberts, Deputy Director of Programs and Operations
Bryan Tomlinson, Director, Division of Health Care Services
Usha Koduru, Counsel to the Board, Office of the Attorney General
Keith Hayashi, RPh, Clinical Pharmacist
Rachel Cain, Pharm.D, Clinical Pharmacist
Maryanne Paccione, Information Management Consultant
Meredith Lee, Policy Analyst
Scott Cannady, Senior Policy Analyst

First Health Staff:
Debbie Moody, R.Ph, Clinical Manager Virginia
Doug Brown, R.Ph, MBA Director Rebate Contracting Management
Sandy Kapur, Pharm.D, Rebate Support
Donna Johnson, R.Ph, Clinical Manager Virginia

Guests:
Marilyn B. Tavenner, Secretary of Health and Human Resources
75 representatives from pharmaceutical companies, providers, advocates, associations, etc

A quorum was present

WELCOME AND INTRODUCTIONS FROM PATRICK FINNERTY, DMAS DIRECTOR

Patrick Finnerty welcomed the Committee and thanked them for all of the work they do in preparation for the meetings. He continued by thanking the representatives from pharmaceutical manufacturers and all of the people that work with DMAS to prepare the meeting. He noted that it takes all parties working together to make the meeting successful. He expressed appreciation for the work that is done by the Committee.

Mr. Finnerty announced that a new contract has been awarded by DMAS for fiscal agent services (the administration of the Medicaid Management Information System) to ACS. The current contract with First Health Services Corporation (FHSC) ends in July 2010. This recently awarded contract was divided into three components. ACS was awarded the fiscal agent services portion of the contract, which is the largest component, and provider enrollment. SXC was awarded the pharmacy rebate contract. Mr. Finnerty indicated that The MMIS is the lifeblood of any Medicaid program and effects more than just pharmacy. FHSC is the current vendor for the PDL and prior authorization program and its contract ends in July of 2010. DMAS is in the process of going through the procurement process for the PDL. All of the new contracts related to the MMIS as well as the PDL program will begin in July of 2010.

DMAS staff have talked to other Medicaid programs across the country to see how they run their PDL programs. DMAS has conducted surveys and talked to provider groups in an effort to get a complete picture of how the agency can make the current process even better. Mr. Finnerty expressed his belief that the current program is the model for the country. The Maximum Allowable Cost (MAC) program will be a part of this procurement as well. Mr. Finnerty asked the Committee members to fill out a new contact

form located in their notebooks. Mr. Finnerty reminded the Committee that their microphones are off unless they hold down the button and to keep it down while a Committee member speaks.

Mr. Finnerty introduced Marilyn Tavenner, the Secretary of Health and Human Resources for the Commonwealth of Virginia, to the Committee. He expressed his delight that she made time in her busy schedule to attend the meeting. He acknowledged that she could not stay for the entire meeting.

COMMENTS AND WELCOME FROM MARILYN TAVENNER THE SECRETARY OF HEALTH AND HUMAN RESOURCES

Secretary Tavenner expressed her appreciation for the work the Committee does. She relayed to the Committee that the work the Committee does with pharmacy is even more critical today. With the number of Medicaid recipients increasing and more people qualifying for Medicaid benefits because of economic hardships, it is even more critical that good decisions and fiscally sound decisions are made to conserve funds so that they are available for other needs. She discussed the work both she and Mr. Finnerty did with the Federal Stimulus package. Their goal was to assure that all Medicaid dollars are being used in the proper manner. She was pleased that the stimulus package allowed them to add back into the budget some benefits that had been cut previously.

Secretary Tavenner discussed the new appointment of the Virginia Technology Secretary Aneesh Chopra to serve as the nation's first Chief Technology Officer. She noted that the appointment was good news for Virginia because there will be a contact in the national Technology Office. She indicated that this appointment may mean more work for her and Mr. Finnerty as they may inherit the health information technology portion of Secretary Chopra's responsibilities.

Dr. Axelrod asked about the amount of increase in Medicaid enrollment. Mr. Finnerty stated that they had completed the year's projection, and in just three months, they had exceeded the official forecast by more than 9,000. Mr. Finnerty indicated that the Medicaid program is growing at such a rapid rate they have had to reforecast enrollment. He reminded the group that Medicaid enrollment is counter cylical to the economy.

COMMENTS AND WELCOME FROM DR. RANDY AXELROD, CHAIRMAN

Dr. Axelrod mentioned that the Committee would be conducting its review of potential new drug classes, the new drugs in phase one of PDL eligible drug classes, and the annual review of phase two PDL drug classes.

Dr. Axelrod noted that some clinical materials received by First Health Services Corporation have copyright protection. These documents cannot be reproduced and included in the P&T Committee members' materials. He asked everyone with access to the documents to safe guard their confidentiality.

Dr. Axelrod indicated that there were 17 presentations on the schedule for the day. He asked that all presenters adhere to the three-minute time limit, using the clock to stay on target.

He asked that the speakers do three things when they come up to address the Committee. First, introduce yourself and say who you are and who you represent. Second, state your affiliation and if you have received any fees or grants from a pharmaceutical manufacturer for your presentation or have any other potential conflicts. Third, discuss only new and pertinent material.

He reminded the Committee that the meeting is being recorded and asked that speakers speak directly into the microphones, and as Mr. Finnerty mentioned, press the button when a member wishes to speak.

ACCEPTANCE OF MINUTES FROM OCTOBER 23, 2008, MEETING

Dr. Axelrod asked if there were any corrections, additions or deletions to the minutes from the October 23, 2008, meeting. With no comments, the minutes were accepted as written.

Drug Class Reviews

To allow practicing physicians to return to their practices, Dr. Axelrod called speakers and reviewed classes in a different order from noted on the agenda.

Phase II PDL Annual Review: Central Nervous System Stimulants/ADHD Medications

Edward John Kuhnley, MD, Child & Adolescent Psychiatrist, Central Virginia Community Services, Lynchburg, VA, discussed Vyvanse® a CNS stimulant medication for ADHD

No questions or comments were provided by the Committee members regarding this presentation.

Potential New Drug Classes: Self-Administered Drug for Rheumatoid Arthritis (RA)

Harry L. Gewanter, M.D., FAAP, FACR Pediatric Rheumatologist- Midlothian, VA, discussed Humira® a Self-Administered Drug for Rheumatoid Arthritis (RA)

Gill Abernathy asked Dr. Gewanter what treatment algorithm he uses when he starts a new patient on medication. Dr. Gewanter responded that they start with Methotrexate as part of their algorithm then add biologics based on response. He noted that there is a new study that illustrates that timing is critical to adding a biological. The earlier you use aggressive treatment the better because if you wait too long then the person begins to get irreversible tissue damage.

Dr. Axelrod commented that he had also seen this same information and that in many illnesses, the sooner you start aggressive therapy the better the outcome, even with physical therapy. Dr. Gewanter noted that he has been in practice and seen three different sets of patients, the pre methotrexate, methotrexate and biological agents. It is possible with early aggressive treatment to shut off the diseases, and have a better outcome.

Barry Tucker, PharmD, Senior Regional Medical Liaison Health Outcomes & Pharmacoeconomics, Amagen discussed Enbrel® a Self-Administered Drugs for Rheumatoid Arthritis (RA)

Ms. Abernathy asked what scales are used to judge the severity of the RA; she thought it might be the number of joints involved. Dr. Tucker answered that the ACR scales are used, it is important to show an improvement from base line.

Ms. Abernathy asked if practicing doctors used these in practice. Dr. Tucker answered that yes they do use them in concept but not documented as they are in studies.

Dr. Gewanter commented that he does use a Health Assessment Questionaire (HAQ) approximately every 6 months to keep up with how people are responding to their medications.

DR. JENNINGS REVIEWED SELF ADMINISTERED DRUGS FOR RHEUMATOID ARTHRITIS (RA)

This is the first time this class is being reviewed. There are a number of products in the class; three are self-injectable Enbrel®, Humira® and Kineret®. Three that are administered intravenously, Raptiva® (that is in the process of being removed from the market), Remicade® and Arnica®. Raptiva® should be excluded because it is being removed from the market, but the rest should be considered PDL eligible.

Dr. Jennings motioned that self-administered drugs for RA class be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider the self-administered drugs for RA class as PDL eligible

From Phase II PDL Annual Review above

MARK OLEY REVIEWED CENTRAL NERVOUS SYSTEM -ANTIHYPERKINESIS/CNS STIMULANTS

Mr. Oley mentioned several points related to this class of drugs. For Dexmethylphenidate HCl ER (Focalin XR®), the FDA has approved a 30-minute onset of action for this medication in the treatment of ADHD. Adderall XR is now available in all strengths as an authorized generic. Procentra solution 5mg/5ml is now available, a liquid version of dextroamphetamine solution.

Mr. Oley motioned that Central Nervous System Antihyperkinesis/CNS Stimulants continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Central Nervous System Antihyperkinesis/CNS Stimulants as PDL eligible.

New Drug PDL Phase I: Lipotropics-Fibric Acid Derivatives

David Duncan, M.D., Internal Medicine, Richmond, VA, discussed Trilipix™ a Lipotropic; Fibric Acid Derivatives

No questions or comments were provided by the Committee members regarding Dr. Duncan's presentation.

GILL ABERNATHY REVIEWED LIPOTROPICS–FIBRIC ACID DERIVATIVES TRILIPIX™

Trilipix™ is a Fenofibric acid molecule formulated with enteric-coated mini-tabs in a capsule for delayed drug release. It is indicated both as monotherapy, as an adjunct to diet, for treatment of patients with mixed dyslipidemia, primary hyperlipidemia, or hypertriglyceridemia and as combination therapy with statins, as an adjunct to diet.
Ms. Abernathy motioned that the new Fibric Acid Derivative, Trilipix™ be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider Trilipix™ a Fibric Acid Derivatives as PDL eligible.

Potential New Drug Classes: Non-Ergot Dopamine Receptor Agonists

Ann Corbin, Associate Director/ National Medical Scientist, CNS Medical Affairs, Boehringer Ingelheim, discussed Mirapex® Non-Ergot Dopamine Receptor Agonists

No questions or comments were provided by the Committee members regarding this presentation.

Melinda Wilson, PharmD, Senior Regional Medical Scientist, GSK Medical Affairs, discussed Requip XL® a Non-Ergot Dopamine Receptor

Dr. Axelrod asked what the levodopa reduction was in the original pre-generic pivotal trial.
GSK staff answered that it was similar, a 20% reduction in levodopa and a 20% reduction in off time. Dr. Axelrod asked in the Requip XL® trial was their no arm that considered a TID dose.
Ann Corbin answered no arm in this study but there is a study in Europe that did look at this.

GILL ABERNATHY REVIEWED NON-ERGOT DOPAMINE RECEPTOR AGONISTS

This is the first time this class is being reviewed. The Committee was charged with determining whether or not this class should be PDL eligible, can these drugs be interchanged. Ms. Abernathy did find that these drugs can be switched with some specifications. If a person has had a hard time being stabilized on a medication then they should be allowed to continue on the drug that they are stable on. In addition, if a person has a difficult time swallowing, then they should be able to continue what they are currently on, while this may not be an issue with the patch, which has been removed from the market.
Dr. Axelrod asked if there is concern about these drugs being used for Restless Leg Syndrome (RLS) instead of Parkinson. The Committee discussed this.

Ms. Abernathy noted that yes there is some concern about them being used for RLS, she asked if there is a way to measure the degree of disability, a scale of some sort.
Dr. Jennings commented that restless leg syndrome has limited information on what the criteria is to establish the diagnosis.
Dr. Axelrod asked if there has been a look-back on how many people using these drugs have Parkinson's Disease.
Sandy Kapur noted across all of the First Health states after Part D recipients went to Medicare Part D an increase has been observed in young recipients receiving one of these products and it is believed that it is for RLS.
Debra Moody noted that looking at just Virginia data, the majority of recipients do have a diagnosis of Parkinson's Disease.
Dr. Axelrod noted that if the class is deemed as PDL eligible that Requip XL® does not have the RLS indication.
Ms. Abernathy motioned that Non-Ergot Dopamine Receptor Agonists class be considered PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Non-Ergot Dopamine Receptor Agonists class as PDL eligible.

Potential New Drug Classes: Multiple Sclerosis Agents

Anne Davis, PharmD, MS, Medical Science Liaison, Biogen Idec |Medical Affairs-Neurology discussed Avonex® a (Interferon Beta 1a) for MS
No questions or comments were provided by the Committee members regarding this presentation.

Christian Lesuisse, PhD, Medical Science Liaison Scientific Affairs, Neuroscience Bayer, discussed Betaseron® a (Interferon Beta 1b) for Multiple Sclerosis
No questions or comments were provided by the Committee members regarding this presentation.

Assad Nasidd, PhD, Medical Science Liaison, Serono Laboratories, discussed Rebif® (interferon Beta 1a)
No questions or comments were provided by the Committee members regarding this presentation.
Dr. Axelrod commented that Multiple Sclerosis admissions are costly and indicated that if a patient is stable it is wise to let them stay as they are.

DR. JENNINGS REVIEWED MULTIPLE SCLEROSIS AGENTS
This is the first time this class is being reviewed. There are four products being considered; three are interferons; Avonex® a β-1a, Rebif® a β-1a and Betaseron® a β-1b the fourth is Copaxone®. It has a different mechanism of action that inhibits T cells. The differences in the products are the dosing and adverse drug reactions (ADRs). The ADRs appear to be dose related. There are a number of head-to-head trials available, some of the earlier trials raised questions concerning a Neutralizing Antibody that was thought to decrease bioavailability after using the product for a period. The most recent trials have shown this not to be the true. One trial did show a slight statistically significant advantage of Rebif® over Avonex® the clinical significance is still not clear. At the same time the ADRs for Rebif® where higher as well.
Dr. Jennings motioned that Multiple Sclerosis Agents class be PDL eligible.
Dr. Axelrod asked if we do decide to restrict the class should grandfathering be considered.
Dr. Jennings replied that he believes these products should be grandfathered.
Ms. Abernathy asked Dr. Jennings to discuss issues with relapse rates seen in trials.
Dr. Jennings explained that one trial did show a slight statistical advantage of Rebif® over Avonex®. He noted that this may be due to the dosing frequency, Rebif® is dosed three times a week verses and Avonex® is once a week. He concluded that with immunosupression the more often you dose the more

suppression you get. At the same time, the more often you dose, the more ADRs you will see, they were higher for Rebif® than Avonex ®
Dr. Beverage asked about the difference between giving IM verses SQ dosing and if this was an issue.
Dr. Jennings stared that he is not aware of any issues because of the dosing route.
Dr. Axelrod asked for the market share between the products.
With the motion seconded, the Committee voted unanimously to consider the Multiple Sclerosis Agents class as PDL eligible.

Phase II PDL Annual Review: Oral Hypoglycemics

Vanessa Land, Medical Services for GlaxoSmithKline Pharmaceuticals, discussed Avandia®, Avandamet® and Avandaryl®, Oral Hypoglycemic Thiazolidinedione (TZD)
Dr. Axelrod commented that Avandia® has been in the news a lot over the past year.
Ms. Land responded that it has and the news this year has been positive.

Dr. Chris Arserver, Medical Director, Merck & Co., discussed Januvia® and Janumet®, DPP4 Inhibitors Oral Hypoglycemic
No questions or comments were provided by the Committee members regarding this presentation.

DR. JENNINGS REVIEWED ORAL HYPOGLYCEMIC
The American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) issued a joint consensus statement on the management of hyperglycemia in patients with type 2 diabetes. The new guidelines recommend a goal hemoglobin A1C of < 7 percent. A first-line therapy is lifestyle intervention and metformin. Step 2 includes the addition of either insulin or sulfonylurea within two to three months of initiating first-line therapy. At any time if target A1C is not achieved, or if metformin is contraindicated, or poorly tolerated, than other therapies will be added. This is the first time a stepwise approach is being recommended.

DR. JENNINGS REVIEWED ALL OF THE ORAL HYPOGLYCEMIC CLASSES TOGETHER
The classes we will be looking at are Second Generation Sulfonylureas, Alpha-Glucosidase Inhibitors, Biguanides (includes combination products), Meglitinides (includes combination products), Thiazolidinediones (TZD) (includes combination products), DPP-IV Inhibitors (includes combination products). There was no change with these classes.
Dr. Jennings motioned that the entire Oral Hypoglycemics class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Oral Hypoglycemics class as PDL eligible.
Dr. Axelrod asked if DMAS would follow the prescribing practices in Virginia to ensure that the new consensus statement is being followed and that metformin is first line. If an issue develops then the Committee will revisit a step edit as discussed last year.

Phase II PDL Annual Review: Analgesics

Laurie J. Cooksey, Pharm.D, Assistant Professor at VCU School of Pharmacy, discussed Celebrex® a Cox-2 Inhibitor
No questions or comments were provided by the Committee members regarding Laurie Cooksey's presentation.

MARK OLEY REVIEWED NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS) (INCLUDES COX-2 INHIBITORS)
Not much change in this class. Most NSAIDs are now available as generics.

Mr. Oley motioned that Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (includes Cox-2 Inhibitors) continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Non-Steroidal Anti-Inflammatory Drugs (includes Cox-2 Inhibitors) as PDL eligible.

Phase II PDL Annual Review: Antibiotics/Anti-Infective

Dean Drosnes, MD, Medical Science Liaison, Hospital Team Global Medical Affairs for Schering-Ploughs discussed Avelox® a Third Generation Quinolone

No questions or comments were provided by the Committee members regarding Dr. Drosnes's presentation.

Heather Crouch, PharmD, Regional Medical Scientist, Glaxo, Smith, Kline (GSK), discussed Relenza® an Influenza Antiviral

No questions or comments were provided by the Committee members regarding Heather Crouch's presentation.

Heather Crouch, PharmD, Regional Medical Scientist, GSK, discussed Altabax® a Topical Antibiotic

No questions or comments were provided by the Committee members regarding Heather Crouch's presentation.

GILL ABERNATHY REVIEWED QUINOLONES-SYSTEMIC

There was no change with this class.
Ms. Abernathy motioned that Quinolone systemic classes continue to be PDL eligible.

GILL ABERNATHY REVIEWED MACROLIDES (INCLUDES KETOLIDES)

There was no change with this class.
Ms. Abernathy motioned that Macrolides (includes Ketolides) classes continue to be PDL eligible.

GILL ABERNATHY REVIEWED ORAL ANTIFUNGALS FOR ONYCHOMYCOSIS

There was no change with this class.
Ms. Abernathy motioned that Oral Antifungals for Onychomycosis class continue to be PDL eligible.

GILL ABERNATHY REVIEWED HERPES ANTIVIRALS

There was no change with this class.
Ms. Abernathy motioned that Herpes Antivirals class continue to be PDL eligible.

GILL ABERNATHY REVIEWED CEPHALOSPORINS SYSTEMIC

There was no change with this class.
Ms. Abernathy motioned that Cephalosporin systemic classes continue to be PDL eligible.

GILL ABERNATHY REVIEWED INFLUENZA ANTIVIRALS

There was no change with this class.
Ms. Abernathy motioned that Influenza Antivirals class continue to be PDL eligible.

DR. JENNINGS REVIEWED TOPICAL ANTIBIOTICS

A new product in the class is Centany™. It is a Topical antibiotic indicated for treatment of impetigo. Centany™ is considered a single source brand product that is not equivalent to Bactroban® Ointment
Dr. Jennings motioned that Topical Antibiotic continue to be PDL eligible.

Dr. Axelrod noted that the Committee made a motion that Herpes Antivirals, Quinolones, Macrolides (includes Ketolides), Oral Antifungals for Onychomycosis, Cephalosporin, Influenza Antivirals and Topical Antibiotic classes continue as PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider all of the classes; Herpes Antivirals, Quinolones, Macrolides (includes Ketolides), Oral Antifungals for Onychomycosis, Cephalosporin, Influenza Antivirals and Topical Antibiotic as PDL eligible.

Phase II PDL Annual Review: Miscellaneous-Serotonin Receptor Agonists (TRIPTANS)

Kristi K. DiRocco, PharmD, Senior Regional Medical Scientist Neuroscience/Urology GSK, discussed Treximet® a Serotonin Receptor Agonists (Triptans)
Dr. Axelrod asked about a statement made concerning using two of the products at the same time. Dr. DiRocco relayed that they were not given at the same time. She apologized for the phrasing.

DR. JENNINGS REVIEWED SEROTONIN RECEPTOR AGONISTS (TRIPTANS)
The only notable changes to class are the new generic for Imitrex and Treximet® being available. Dr. Jennings motioned that the Serotonin Receptor Agonists (Triptans) class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Serotonin Receptor Agonists (Triptans) class as PDL eligible.

Phase II PDL Annual Review: Osteoporosis-Bisphosphonates

Sharon Smith, Pharm D., Medical Liaison, Roche, discussed Boniva® a Bisphosphonate
No questions or comments were provided by the Committee members regarding this presentation.

DR. JENNINGS REVIEWED OSTEOPOROSIS BISPHOSPHONATES
There were no changes to this class with the exception of Fosamax® , which is now generic. The change to the generic was a smooth transition.
Dr. Jennings motioned that the entire Osteoporosis Bisphosphonates class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Osteoporosis Bisphosphonates class as PDL eligible.

Potential New Drug Classes: Otic Quinolones

DR. JENNINGS REVIEWED OTIC QUINOLONES
The Otic Quinolones is a new class being reviewed for the first time. It will join the Current Quinolones classes of oral & ophthalmic classes that are reviewed every spring; the products being reviewed are Ciprodex®, Cipro HC® Floxin® and Ofloxacin (generic for Floxin®). Dr. Jennings motioned that Otic Quinolones class be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Otic Quinolones class as PDL eligible.

Potential New Drug Classes: Topical Antivirals

DR. JENNINGS REVIEWED TOPICAL ANTIVIRALS
The Topical antiviral is a new class being reviewed for the first time. It joins the current class of Oral Antivirals that is reviewed every spring; the products being reviewed are Abreva OTC, Denavir, Zovirax cream and Zovirax oint. Treatments for Viral out breaks can be either topical or oral regimens. Dr. Jennings motioned that Topical antiviral class be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Topical antiviral class as PDL eligible.

Potential New Drug Classes: Intranasal Antihistamines

DR. JENNINGS REVIEWED INTRANASAL ANTIHISTAMINES

The Intranasal Antihistamines is a new class being reviewed for the first time. It joins the current class Nasal corticosteroid, which is reviewed every fall. The Nasal corticosteroids are first line therapy. The products being reviewed are Astepro, Astelin and Patanase. Dr. Jennings motioned that Intranasal Antihistamines class be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Intranasal Antihistamines class as PDL eligible.

Potential New Drug Classes: Calcitonins

DR. JENNINGS REVIEWED CALCITONINS

Calcitonins is a new class being reviewed for the first time.I It joins the current class Bisphosphonates - that is reviewed every spring. The products being reviewed are Calcitonin-salmon (generic Miacalcin®), Fortical® and Miacalcin®. Dr. Jennings motioned that Calcitonins class be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Calcitonins class as PDL eligible.

Potential New Drug Classes: Gout Suppressants

GILL ABERNATHY REVIEWED GOUT SUPPRESSANTS (ANTIHYPERURICEMICS)

This is the first time this class is being reviewed the products being considered are Allopurinol and Uloric. Ms. Abernathy motioned that Gout Suppressants class be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Gout Suppressants class as PDL eligible.

Potential New Drug Category: Dermatologic Products

MARK OLEY REVIEWED DERMATOLOGIC PRODUCTS INCLUDING ACNE AND PSORIASIS

Acne products include Combination Benzoyl Peroxide, Clindamycin and Topical Retinoids. All products are indicated for the topical treatment of acne vulgaris. Tazorac additionally is indicated for the treatment of plaque psoriasis. The Benzoyl Peroxide and Clindamycin Combinations products are Duac® Gel, Duac® CS – CS and Benzaclin® Gel. Topical Retinoids agents are Tretinoin, Tretin-X, Adapalene, and Tazarotene Combination products are Ziana™ and Epiduo®. Mr. Oley stated that Tazarotene (Tazorac) is a teratogenic substance and classified as Pregnancy Category X. In summary, Mr. Olney indicated that topical retinoids are the first choice for treatment of acne. The person should be informed that it might take between 2 to 4 weeks for the products to be effective.

Psoriasis agents include Vectical™, Dovonex®, Taclonex®, Taclonex® Scalp, and Psoriatec, ® Valid comparable trials are lacking. Mr. Oley motioned that Acne (including Combination Benzoyl Peroxide & Clindamycin & Topical Retinoids) and Topical Agents for Psoriasis class be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Acne (including Combination Benzoyl Peroxide & Clindamycin & Topical Retinoids) and Topical Agents for Psoriasis class as PDL eligible.

Review of New Drugs in PDL Phase I: Electrolyte Depleters

GILL ABERNATHY REVIEWED NEW ELECTROLYTE DEPLETERS CALCIUM ACETATE 667MG AND ELIPHOS

Ms. Abernathy stated that the new generic product calcium acetate in the same strength as Phoslo and a new brand name drug Eliphos.

Ms. Abernathy motioned that the new Electrolyte Depleters Calcium acetate 667mg and Eliphos be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider new Electrolyte Depleters Calcium acetate 667mg and Eliphos as PDL eligible.

MARK OLEY REVIEWED THE NEW FIRST TIME GENERIC CORTICOSTEROID NEBULIZER SOLUTIONS BUDESONIDE

A new first time generic solution, Budesonide inhalation suspension (Pulmicort Respules®), is now available generically.
Mr. Oley motioned that the new first time generic Corticosteroid Nebulizer solutions Budesonide be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider new first time generic Corticosteroid Nebulizer solutions Budesonide as PDL eligible.

MARK OLEY REVIEWED PROTON PUMP INHIBITORS PRILOSEC® SUSPENSION AND KAPIDEX®

Kapidex® is a proton pump inhibitor that is an enantiomer of Prevacid® (lansoprazole). It is available as a delayed-release capsule. There are no comparative data to support the use of Kapidex® over another PPI; therefore, cannot prove a definitive benefit over other PPI agents. Only notable difference is that the capsules may be taken without regards to meals. Prilosec® suspension is a new formulation of Prilosec®. PPIs and Plavix® the FDA is currently looking into a possible concerns Plavix® metabolism when used with a PPI. For now the word is to until further information is available, which could be months, healthcare providers should continue to prescribe and patients should continue to take Plavix® as directed. Providers and their patients should also re-evaluate together the need for initiating or continuing Plavix® in combination with a PPI, including Prilosec OTC®.
Ms. Abernathy commented that this is a concern in the medical community.
Mr. Oley motioned that the new Proton Pump Inhibitors Prilosec® suspension and Kapidex® be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider new PROTON Pump Inhibitors Prilosec® susp & Kapidex® as PDL eligible

MARK OLEY REVIEWED THE URINARY TRACT ANTISPASMODICS TOVIAZ™

Toviaz™ is a new drug it is a competitive muscarinic receptor antagonist indicated for treatment of overactive bladder (OAB). Toviaz enters a market that has a number of products already available, there are no head-to-head studies involving these agents and only limited studies comparing immediate-release and extended-release products.
Mr. Oley motioned that the new Urinary Tract Antispasmodics Toviaz™ be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider Toviaz™ a Urinary Tract Antispasmodics as PDL eligible.

MARK OLEY REVIEWED LEUKOTRIENE (MODIFIERS & FORMATION INHIBITORS)

There was no change with this class.
Mr. Oley motioned that - Leukotriene (Modifiers & Formation Inhibitors) class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider - Leukotriene (Modifiers & Formation Inhibitors) as PDL eligible.

Phase II PDL Annual Review: Long-Acting Narcotics

Dr. Jennings began a discussion with the Committee on quantity limits on brand Long Acting Narcotics. It was determined that the Committee has reviewed and discussed this in the past; in the end, it is difficult to place a quantity limit on total dose because there is no ceiling for these products. The Committee may want to discus and consider reevaluation of branded products at some time because they are promoted by Pharma and do have abuse potential.

MARK OLEY REVIEWED LONG ACTING NARCOTICS

There was no change with this class.
Mr. Oley motioned that Long Acting Narcotics continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Long Acting Narcotics as PDL eligible.

MARK OLEY REVIEWED OPHTHALMICS GLAUCOMA (INCLUDES ALPHA-2 ADRENERGIC, BETA-BLOCKERS, CARBONIC ANHYDRASE INHIBITORS & PROSTAGLANDIN ANALOGS)

Two new generics are now Trusopt® Solution and Cosopt® solution.

MARK OLEY REVIEWED OPHTHALMIC ANTI-INFLAMMATORY (NSAID)

There was no change with this class.

MARK OLEY REVIEWED OPHTHALMI ANTIBIOTICS (INCLUDING -QUINOLONES & MACROLIDES)

Change to this class is addition of the Macrolide - AzaSite™ (azithromycin). AzaSite is a topical ophthalmic solution.

MARK OLEY REVIEWED OPHTHALMIC -ALLERGIC CONJUNCTIVITIS (INCLUDES ANTIHISTAMINES & MAST CELL STABILIZERS)

Mr. Oley motioned that all of the Ophthalmic products, Allergic conjunctivitis (Includes Antihistamines & Mast Cell Stabilizers), Glaucoma (Includes Alpha-2 Adrenergic, Beta-blockers, Carbonic Anhydrase Inhibitors & Prostaglandin Analogs), Ophthalmic Anti-Inflammatory (NSAID), Allergic conjunctivitis (Includes Antihistamines & Mast Cell Stabilizers) continue to be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider ophthalmic products as stated as PDL eligible.

COMMENTS FROM OFFICE OF THE ATTORNEY GENERAL

Ms. Usha Koduru from the Attorney General's office stated that under the Virginia Freedom of Information Act (FOIA), specifically Virginia Code section 2.2-3711, a public body such as the P&T Committee, may go into a closed session for any of the 42 reasons listed in that statute. The discussion of manufacturer and wholesaler prices is not one of the 42 reasons listed.

She stated the Attorney General strongly supports the principles of open government embodied by the FOIA and believes in the opportunity of the Commonwealth's citizens to witness the operation of government to the fullest extent.

Federal Law 42 U.S.C. 1396r-8(b) (3) (D) requires such pricing information to be kept confidential. On this point, federal law supersedes the Virginia FOIA. Since the P&T Committee must discuss this pricing information as part of its duties, pursuant to federal law a confidential meeting must occur for the consideration of this pricing information she cautioned only this confidential information should be discussed.

Mr. Oley made a motion for the P&T Committee to resume the meeting in another room to discuss this confidential information regarding prices charged by the manufacturers and wholesalers of the drug classes discussed at this P&T Committee meeting. This confidential meeting is authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential.

This motion was seconded and unanimously approved by the Committee.

The meeting adjourned to an executive session.

The Committee returned to the room.

Dr. Axelrod confirmed that to the best of each of the Committee member's knowledge the only information discussed at the confidential meeting was information regarding prices charged by the manufacturers and wholesalers of the drug classes discussed at this P&T Committee meeting. As authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential.

The motion was made to resume the meeting. The motion was seconded and unanimously approved by the Committee.

GENERIC WATCH AND NEW DRUGS IN PHASE I REVIEW

Dr. Axelrod made a motion to accept the Generic policy and new drugs in phase I recommendations for no changes to be made to the following classes Alpha- Glucoside Inhibitors, Antivirals, Long Acting Narcotic, CNS/ADHD Medications, Glaucoma Agents, Proton Pump Inhibitors, Corticosteroid Nebulizer solutions, Electrolyte Depleters, Triptans, Lipotropics–Fibric Acid Derivatives, and Urinary Tract Antispasmodics. With the motion seconded, the Committee voted unanimously to maintain the current mentioned classes with no changes.

Dr. Axelrod made a motion to accept the following changes that occurred per the Generic policy and new drugs in phase I recommendations:

- Ophthalmic Anti-inflammatory to make Diclofenac Sodium preferred and Voltaren Non Preferred,
- CCB/ACEI Combinations the strengths 5/40 and 10/40 the Brand Lotrel will be preferred, for the rest of the strengths the generic will be preferred,
- COPD Anticholinergics to make Ipratropium preferred and Atrovent Non Preferred,
- Move the Macrolides brands to preferred when the generics are preferred but no generics are available.

With the motion seconded, the Committee voted unanimously to make the changes as noted above.

PDL NEW CLASSES AND NEW CATAGORIES TO START JULY 1, 2009

In current category of Antibiotics

Dr. Jennings made a motion to add the new class of Otic Quinolones to the current PDL with Ciprodex® and ofloxacin as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

In new category Immunologic agent

Dr. Jennings made a motion to add the new class of Self-Administered drugs for RA to the current PDL with Enbrel® AND Humira® as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

In new category of Dermatological

Dr. Jennings made a motion to add the new class of Combo benzoyl peroxide & Clindamycin to the current PDL with Duac® CS the single preferred agent as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

In new category of Dermatologic

Dr. Jennings made a motion to add the new class of Topical Retinoids/Combinations to the current PDL with Differin® 1%cream, 1% & 0.3% gel, Retin®-A Micro, Retin®-A Micro Pump, Tretinoin®, Epiduo® as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

In new category of Dermatologic
Dr. Jennings made a motion to add the new class of Topical Antivirals to the current PDL with Abreva® OTC and Zovirax® Ointment as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

In new category of Dermatological
Dr. Jennings made a motion to add the new class of Topical Agents for Psoriasis to the current PDL with Calcipotriene® scalp, Dovonex® and Psoriatec® as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

In current category of Osteoporosis
Dr. Jennings made a motion to add the new class of Calcitonins to the current PDL with Fortical® and Miacalcin® as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

In a new category Immunologic agent
Dr. Jennings made a motion to add the new class of Multiple Sclerosis Agents to the current PDL with Avonex®, Avonex® Adm Pack, Betaseron®, Copaxone® and Rebif ®as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products. Dr. Axelrod commented that the committee will continue to follow Multiple Sclerosis Agents and discuss it again at the fall meeting.

In current category of Asthma-Allergy
Dr. Jennings made a motion to add the new class of Intranasal Antihistamines to the current PDL with Astelin® and Astepro® as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

In current category of Central Nervous System
Dr. Jennings made a motion to add the new class of Non-Ergot Dopamine Receptor Agonists to the current PDL, with Mirapex® and ropinirole as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

In current categoryMisscellaneous
Dr. Jennings made a motion to add the new class Oral Agents for Gout to the current PDL, with allopurinol as the preferred agent. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

Phase II PDL Annual Review ~ PDL Status Changes Effective July 1, 2009
Dr. Jennings made a motion to maintain the current PDL Serotonin Receptor Agonists (Triptans) class with no change but to review financials in the fall. With the motion seconded, the Committee voted unanimously to maintain the current Serotonin Receptor Agonists (Triptans) with no change.

Dr. Jennings made a motion to maintain the current PDL ADHD Amphetamine Products class with no change. With the motion seconded, the Committee voted unanimously to maintain the current ADHD Amphetamine Products with no change.

Dr. Jennings made a motion to maintain the current PDL ADHD Methylphenidate Products class with no change. With the motion seconded, the Committee voted unanimously to maintain the current ADHD Methylphenidate Products with no change.

Dr. Jennings made a motion to maintain the current PDL ADHD Miscellaneous Products class with no change. With the motion seconded, the Committee voted unanimously to maintain the current ADHD Miscellaneous Products with no change.

Dr. Jennings made a motion to make a change to the current PDL Ophthalmic Antihistamines class, to make Alaway OTC® the only preferred product and all of the others will move to non-preferred. With the motion seconded, the Committee voted unanimously to make the changed as noted.

Dr. Jennings made a motion to make a change to the current PDL class Macrolides to move clarithromycin ER to non-preferred. With the motion seconded, the Committee voted unanimously to make the changed as noted.

Dr. Jennings made a motion to make a change to the current PDL class Ophthalmic Prostaglandin Analogs to move Lumigan® 0.03% drops to non-preferred. With the motion seconded, the Committee voted unanimously to make the changed as noted.

Dr. Jennings made a motion to make a change to the current PDL class Antibiotics: systemic Cephalosporins to move Cedax Capsule® and Cedax Suspension® to non-preferred and Suprax Suspension® to a preferred status. With the motion seconded, the Committee voted unanimously to make the changed as noted.

Dr. Jennings made a motion to make a change to the current PDL class Bisphosphonates to move Fosamax plus D® to non-preferred. With the motion seconded, the Committee voted unanimously to make the changed as noted.

Dr. Jennings made a motion to make a change to the current PDL NSAIDs (Non-Steroidal Anti-inflammatory Drugs) class, to move meloxicam to preferred. With the motion seconded, the Committee voted unanimously to make the changed as noted.

Dr. Jennings made a motion to make a change to the current PDL class LAN to move Avinza® to non-preferred and Kadian® to a preferred status. With the motion seconded, the Committee voted unanimously to make the changed as noted.

Dr. Jennings made a motion to make a change to the current PDL class Topical Antibiotics to move Altabax® 5 gram to preferred. With the motion seconded, the Committee voted unanimously to make the changed as noted.

Dr. Jennings made a motion to maintain the current PDL Ophthalmic Anti-Inflammatory class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Ophthalmic Anti-Inflammatory with no change.

Dr. Jennings made a motion to maintain the current PDL Ophthalmic Antibiotics (Fluoroquinolones & Macrolides) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Ophthalmic Antibiotics (Fluoroquinolones & Macrolides) with no change.

Dr. Jennings made a motion to maintain the current PDL ophthalmic glaucoma agent (including Alpha Two Adrenergic Agents, Beta Blockers, and Carbonic Anhydrase Inhibitors) classes with no change. With the motion seconded, the Committee voted unanimously to maintain the current ophthalmic glaucoma agent noted with no change.

Dr. Jennings made a motion to maintain the current PDL Ophthalmic Mast Cell Stabilizers class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Ophthalmic Mast Cell Stabilizers with no change.

Dr. Jennings made a motion to maintain the current PDL Oral Hypoglycemic agents (including classes Alpha-Glucosidase Inhibitors, Second Generation Sulfonylureas, Biguanides and Biguanide Combination Products, DPP-IV inhibitors and combination class, Meglitinides and Meglitinides Combination Products, Thiazolidinediones and Thiazolidinediones Combination with no change. With the motion seconded, the Committee voted unanimously to maintain the current Oral Hypoglycemic agents noted with no change.

Dr. Jennings made a motion to maintain the current PDL Antibiotic and anti-infective classes (including all systemic Quinolones, systemic Cephalosporins, Oral Antifungals used for Onychomycosis, Antivirals for Herpes or Influenza) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Antibiotic and anti-infective classes with no change.

Dr. Jennings made a motion to maintain the current PDL Leukotriene Receptor Antagonists class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Leukotriene Receptor Antagonists with no change.

The Committee decided to have an electronic look back for the Cox-2 Inhibitors clinical edit and Celebrex® will be included in the NSAIDS (Non-Steroidal Anti-inflammatory Drugs) list of products.

CRITERIA DISCUSSION OF THE NEW CLASSES

Dr. Axelrod reviewed the new purposed criteria with the Committee; with no changes recommended, a motion was made to accept the criteria as written. With the motion seconded, the Committee voted unanimously to accept the new criteria with no change.

CRITERIA DISCUSSION OF PHASE I AND PHASE II

Dr. Axelrod reviewed the current Phase I criteria for the new drugs in Phase I with the Committee, with no changes recommended a motion was made to accept as written. With the motion seconded, the Committee voted unanimously to accept the current criteria with no change.

Dr. Axelrod made note of the LAN step edit in reference to the earlier discusses on quantity limits.

Dr. Axelrod reviewed the current Phase II criteria with the committee, with no changes recommended a motion was made to accept as written. With the motion seconded, the Committee voted unanimously to accept the current criteria with no change.

Dr. Axelrod noted that the next meeting would be in the fall of 2009. The meeting was adjourned.